

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

						Introduction Type:	Post Launch Change		x Final Version			Date:	6/23	, 202 1
			PRODUCT INFORMA	ATION					SPECIAL HAN	IDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	euticals				Application:	ANDA	a. Temperatu	re - Indicate the USP temp	erature range for th	nis product.			
Application Number for NDA/AN			ice):	2119	977				Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applica		, ,,	·					†	, ,					
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na	me: Esom	neprazole Magnesium Delaye	ed-Release Capsul	les, USP 20 mg	3		T	(write in)	•				
Selling Unit NDC:	31722-664-90		Unit of Use NDC:	: 3	31722-664-90		722664905	1	Notes					
UDI			CVX Code:			MVX Code:		I						
Description:	Esomeorazole Ma	gnesium Delayed-R	elease Capsules, USP 20 m	ıa				ī	Is this product to be shippe	d to customers on ic	e?		No	1
		g, ,		9					Is this product to be shippe				No	
Active Ingredient(s):		Esomeprazole ma	gnesium trihydrate, USP					†			•			-
							b. Contact fo	r temperature excursion qu	estions:					
URL for Additional Product Inform	mation:	www.camberpharm	na.com					I	Name:		Soma Raju			
Address:	800 Centennial Av	re, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway				State:	NJ Zip	08854		Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	Customer Service				Email:	customerservice@cam	berpharma.com							1
Phone Number:	1-866-827-3647	Destar and taken	' (DDI)		Fax:	732-562-8788		c. Special reg	gulations for product in any				No	-
Product Therapeutic Classification	on:	Proton pump inhib	itor (PPI)						Special returns requirement	ts for this product?			No	
	ADDITIO	ONAL PRODUCT IN	IFORMATION.			BRODUST BESS	PRINTION INFORMATION							1
	ADDITIO	ONAL PRODUCT IN				PRODUCT DESC	RIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship On	nly				Protect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	90 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						Initial shelf life at launch (if different):				Months
a product kit?		No	ED 4 4 101-11-1			Strength:	20 mg			ORDER INFORM	ATION			
if yes, list NDCs of			FDA Approval Status				Hard gelatin, delayed-			OKDEK INFORM	ATION			
component parts reverse numbered?		No				Dosage Form:	release capsule		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present				release capsule		x Bottle		1 Bottle of 9		uiiit.	
latex-free?		Yes	_				Capsule		Box/Carton			g. 1 Box of 1) Vials)	
preservative-free?		Yes	Alcohol, Anima	al Products, Suga	ır	Product Shape:	5.07.5		Ampule		(,	,	
correctional institution block?		No				Product Color:	White opaque cap and		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:	white opaque body		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Imprinted with 'H' on cap		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					r roduct imprint.	and 'E2' on body		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?														
			Is this product covered to						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Is this product covered to Trade Agreements Act (No				Vial Powder Multi			Inner/Carton	/Pack	
			Trade Agreements Act ((AAT)?	No								/Pack	
				(AAT)?	No				Vial Powder Multi			Inner/Carton	/Pack	
			Trade Agreements Act ((AAT)?					Vial Powder Multi Other: Write In	MARIA AV ARRES		Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act ((AAT)?			uthorized Generic, other		Vial Powder Multi Other: Write In	IARMACY ORDER	/ BILL UNIT	Inner/Carton Case		
If Unit Dose, indicate NDC here:	AB		Trade Agreements Act ((AAT)?			uthorized Generic, other ion fields are not applicable	Rec. sell unit	Vial Powder Multi Other: Write In	HARMACY ORDER		Inner/Carton Case		
If Unit Dose, indicate NDC here:		Nexium	Trade Agreements Act ((AAT)?					Vial Powder Multi Other: Write In PH to customer?	IARMACY ORDER	/ BILL UNIT	Inner/Carton Case nit to pharma Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act ((TAA)?	Auth			Rec. sell unit	Vial Powder Multi Other: Write In PH to customer?	IARMACY ORDER	/ BILL UNIT	Inner/Carton Case hit to pharma Each Gram		
If Unit Dose, indicate NDC here:			Trade Agreements Act ((TAA)?	Auth				Vial Powder Multi Other: Write In PH to customer?	IARMACY ORDER	/ BILL UNIT	Inner/Carton Case nit to pharma Each		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT	(DSCSA) INFORM	Auth	sect			Vial Powder Multi Other: Write In Place to customer?		/ BILL UNIT Rx billing u	Inner/Carton Case hit to pharma Each Gram Milliliter		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	DRUG SUPP	Trade Agreements Act ((DSCSA) INFORM	Auth				Vial Powder Multi Other: Write In Place to customer?	HARMACY ORDER	/ BILL UNIT Rx billing u	Inner/Carton Case hit to pharma Each Gram Milliliter		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA?	and?:	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes	(DSCSA) INFORM	Auth	sect			Vial Powder Multi Other: Write In Place to customer?	I AND PACKING IN	/ BILL UNIT Rx billing un	Inner/Carton Case nit to pharma Each Gram Milliliter	acy:	Salashia "
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption:	and?:	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes	(DSCSA) INFORM	Auth	sect			Vial Powder Multi Other: Write In Place to customer?	M AND PACKING IN	/ BILL UNIT Rx billing un	Inner/Carton Case nit to pharma Each Gram Milliliter	acy:	Saleable #
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?:	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No	(DSCSA) INFORM	Auth MATION GLN: GCP:	0331722498975	ion fields are not applicable	(Write-in, e.g	Vial Powder Multi Other: Write In PH to customer? 1 Vial) ITEL Weight Lbs.	II AND PACKING IN Dimensie Depth	/ BILL UNIT Rx billing un IFORMATION Ons (US msm Width	Inner/Carton Case hit to pharma Each Gram Milliliter	Volume (Cube)	Pieces
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: ition of manufactur	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes	(DSCSA) INFORM	Auth MATION GLN: GCP: If yes, was orig	0331722498975	ion fields are not applicable		Vial Powder Multi Other: Write In Pt to customer? . 1 Vial)	M AND PACKING IN	/ BILL UNIT Rx billing un	Inner/Carton Case nit to pharma Each Gram Milliliter	acy:	
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	and?: ition of manufactur	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No	(DSCSA) INFORM	MATION GLN: GCP: If yes, was originated from mfr	0331722498975 ginal product purchase	ion fields are not applicable	(Write-in, e.g	Vial Powder Multi Other: Write In PH to customer? 1 Vial) Weight Lbs. 0.13	II AND PACKING IN Dimensie Depth	/ BILL UNIT Rx billing un IFORMATION Ons (US msm Width	Inner/Carton Case hit to pharma Each Gram Milliliter	Volume (Cube)	Pieces
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: ition of manufactur s exclusive distribu	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR PLY CHAIN SECURITY ACT Yes No No Yes	(DSCSA) INFORM	MATION GLN: GCP: If yes, was originated from mfr	0331722498975	ion fields are not applicable	(Write-in, e.g	Vial Powder Multi Other: Write In PH to customer? 1 Vial) Weight Lbs. 0.13	II AND PACKING IN Dimensie Depth	/ BILL UNIT Rx billing un IFORMATION Ons (US msm Width	Inner/Carton Case hit to pharma Each Gram Milliliter	Volume (Cube)	Pieces
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	and?: ition of manufactur s exclusive distribu	er? tor? oduct?	Trade Agreements Act (FOR GENERIC DRUG PR PLY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	MATION GLN: GCP: If yes, was originated from mfr	0331722498975 ginal product purchase	ion fields are not applicable	(Write-in, e.g	Vial Powder Multi Other: Write In Photo customer? .1 Vial) Weight Lbs. 0.13 Bundle/	I AND PACKING IN Dimensic Depth 1.9	/ BILL UNIT Rx billing us IFORMATION Ons (US msm Width 1.9	Inner/Carton Case iit to pharma Each Gram Milliliter Height 3.27	Volume (Cube)	Pieces 1
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	and?: ition of manufactur s exclusive distribu	er? tor? oduct?	Trade Agreements Act (FOR GENERIC DRUG PR PLY CHAIN SECURITY ACT Yes No No Yes	(DSCSA) INFORM	MATION GLN: GCP: If yes, was originated from mfr	0331722498975 ginal product purchase	ion fields are not applicable	(Write-in, e.g	Vial Powder Multi Other: Write In PH to customer? 1 Vial) Weight Lbs. 0.13	II AND PACKING IN Dimensie Depth	/ BILL UNIT Rx billing un IFORMATION Ons (US msm Width	Inner/Carton Case hit to pharma Each Gram Milliliter	Volume (Cube)	Pieces
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	Authon GLN: GCP: If yes, was originated from mfr. Provide source	0331722498975 ginal product purchaser? e manufacturer for rep	ed ackaged product	(Write-in, e.g	Vial Powder Multi Other: Write In Photo customer? .1 Vial) Weight Lbs. 0.13 Bundle/	I AND PACKING IN Dimensic Depth 1.9	/ BILL UNIT Rx billing us IFORMATION Ons (US msm Width 1.9	Inner/Carton Case iit to pharma Each Gram Milliliter Height 3.27	Volume (Cube)	Pieces 1
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP er? tor? oduct? GT aleable Quantity	Trade Agreements Act (FOR GENERIC DRUG PR PLY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	MATION GLN: GCP: If yes, was originated from mfinerect from mfinerect from control of the cont	0331722498975 ginal product purchaser? e manufacturer for rep	ion fields are not applicable ackaged product Unit of Use GTIN-14	(Write-in, e.g	Vial Powder Multi Other: Write In Photo customer? .1 Vial) Weight Lbs. 0.13 Bundle/	I AND PACKING IN Dimensic Depth 1.9	/ BILL UNIT Rx billing us IFORMATION Ons (US msm Width 1.9	Inner/Carton Case iit to pharma Each Gram Milliliter Height 3.27	Volume (Cube)	Pieces 1
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Brains product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception if yes, attach documentation from Saleable Unit of Measure	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	MATION GLN: GCP: If yes, was originated from mfinerect from mfinerect from control of the cont	0331722498975 ginal product purchaser? e manufacturer for rep	ed ackaged product	(Write-in, e.g	Vial Powder Multi Other: Write In PH Ito customer? .1 Vial) Weight Lbs. 0.13 Bundle/ 3.5	I AND PACKING IN Dimensic Depth 1.9	/ BILL UNIT Rx billing un IFORMATION Ons (US msm Width 1.9	Inner/Carton Case hit to pharma Each Gram Milliliter Its.) Height 3.27	Volume (Cube) 11.80	Pieces 1 24
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption: Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiever/exceptio If yes, attach documentation fro Saleable Unit of Measure X	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP er? tor? oduct? GI aleable Quantity	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	Authon GLN: GCP: If yes, was originated from min Provide source GTIN 0033	0331722498975 ginal product purchaser? e manufacturer for rep	ion fields are not applicable ackaged product Unit of Use GTIN-14	(Write-in, e.g	Vial Powder Multi Other: Write In Photo customer? .1 Vial) Weight Lbs. 0.13 Bundle/	I AND PACKING IN Dimensic Depth 1.9	/ BILL UNIT Rx billing un IFORMATION Ons (US msm Width 1.9	Inner/Carton Case hit to pharma Each Gram Milliliter Its.) Height 3.27	Volume (Cube)	Pieces 1 24
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X Item/Each Bow/Carton/Bundle/Inner Pack X Case	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP er? tor? oduct? GT aleable Quantity	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	Authon GLN: GCP: If yes, was originated from min Provide source GTIN 0033	0331722498975 ginal product purchaser? e manufacturer for rep	ion fields are not applicable ackaged product Unit of Use GTIN-14	(Write-in, e.g	Vial Powder Multi Other: Write In Property to customer? 1 Vial) Weight Lbs. 0.13 Bundle/ 3.5 COST INFORMATION	I AND PACKING IN Dimensic Depth 1.9	FORMATION (US msm Width 1.9	Inner/Carton Case hit to pharma Each Gram Milliliter Its.) Height 3.27	Volume (Cube) 11.80	Pieces 1 24
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption: Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiever/exceptio If yes, attach documentation fro Saleable Unit of Measure X	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP er? tor? oduct? GI aleable Quantity	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	Authon GLN: GCP: If yes, was originated from min Provide source GTIN 0033	0331722498975 ginal product purchaser? e manufacturer for rep	ion fields are not applicable ackaged product Unit of Use GTIN-14	Item/Each: Box/Carton/Einner Pack: Case: Pallet:	Vial Powder Multi Other: Write In PH Ito customer? 1 Vial) ITEN Weight Lbs. 0.13 Bundle/ 3.5 COST INFORMATION	Dimension Depth 1.9	/ BILL UNIT Rx billing un FORMATION ons (US msm Width 1.9 8	Inner/Carton Case hit to pharma Each Gram Milliliter Ints.) Height 3.27 4.5	Volume (Cube) 11.80	Pieces 1 24
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X Item/Each Bow/Carton/Bundle/Inner Pack X Case	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP er? tor? oduct? GI aleable Quantity	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	Authon GLN: GCP: If yes, was originated from min Provide source GTIN 0033	0331722498975 ginal product purchaser? e manufacturer for rep	ion fields are not applicable ackaged product Unit of Use GTIN-14	(Write-in, e.g	Vial Powder Multi Other: Write In PH Ito customer? 1 Vial) ITEN Weight Lbs. 0.13 Bundle/ 3.5 COST INFORMATION	Dimension Depth 1.9 11.75	/ BILL UNIT Rx billing us IFORMATION Ons (US msm Width 1.9 8	Inner/Carton Case iit to pharma Each Gram Milliliter Its.) Height 3.27	Volume (Cube) 11.80	Pieces 1 24
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X Item/Each Bow/Carton/Bundle/Inner Pack X Case	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP er? tor? oduct? GI aleable Quantity	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	Authon GLN: GCP: If yes, was originated from min Provide source GTIN 0033	0331722498975 ginal product purchaser? e manufacturer for rep	ion fields are not applicable ackaged product Unit of Use GTIN-14	(Write-in, e.g Item/Each: Box/Carton/E Inner Pack: Case: Pallet: Regular Cost Invoice Cost	Vial Powder Multi Other: Write In PH Ito customer? 1 Vial) ITEN Weight Lbs. 0.13 Bundle/ 3.5 COST INFORMATION	Dimension Depth 1.9 11.75	/ BILL UNIT Rx billing un FORMATION ons (US msm Width 1.9 8	Inner/Carton Case iit to pharma Each Gram Milliliter Its.) Height 3.27	Volume (Cube) 11.80	Pieces 1 24
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X Item/Each Bow/Carton/Bundle/Inner Pack X Case	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP er? tor? oduct? GI aleable Quantity	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	Authon GLN: GCP: If yes, was originated from min Provide source GTIN 0033	0331722498975 ginal product purchaser? e manufacturer for rep	ion fields are not applicable ackaged product Unit of Use GTIN-14	Item/Each: Box/Carton/Einner Pack: Case: Pallet:	Vial Powder Multi Other: Write In Property to customer? 1 Vial) Weight Lbs. 0.13 Bundle/ 3.5 COST INFORMATION (WAC) (\$)	Dimension Depth 1.9 11.75	/ BILL UNIT Rx billing us IFORMATION Ons (US msm Width 1.9 8	Inner/Carton Case iit to pharma Each Gram Milliliter Its.) Height 3.27	Volume (Cube) 11.80	Pieces 1 24
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X Item/Each Bow/Carton/Bundle/Inner Pack X Case	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP er? tor? oduct? GI aleable Quantity	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No No Yes No	(DSCSA) INFORM	Authon GLN: GCP: If yes, was originated from min Provide source GTIN 0033	0331722498975 ginal product purchaser? e manufacturer for rep	ion fields are not applicable ackaged product Unit of Use GTIN-14	(Write-in, e.g Item/Each: Box/Carton/E Inner Pack: Case: Pallet: Regular Cost Invoice Cost	Vial Powder Multi Other: Write In Property to customer? 1 Vial) Weight Lbs. 0.13 Bundle/ 3.5 COST INFORMATION (WAC) (\$)	Dimension Depth 1.9 11.75	/ BILL UNIT Rx billing us IFORMATION Ons (US msm Width 1.9 8	Inner/Carton Case iit to pharma Each Gram Milliliter Its.) Height 3.27	Volume (Cube) 11.80	Pieces 1 24
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro Saleable Unit of Measure X Item/Each Bow/Carton/Bundle/Inner Pack X Case	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPP er? tor? oduct? GI aleable Quantity	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No Yes No TIN AND HIBCC PRODUCT I HIBCC	(DSCSA) INFORM	MATION GLN: GCP: If yes, was originated from mfr Provide source GTIN 0033 2033	0331722498975 0331722498975 ginal product purchaser? e manufacturer for rep 1-14 1722664905 1722664909	ion fields are not applicable ackaged product Unit of Use GTIN-14	[Write-in, e.g.] Item/Each: Box/Carton/Itemer Pack: Case: Pallet: Regular Cost Invoice Cost As of date:	Vial Powder Multi Other: Write In Proto customer? 1 Vial) Weight Lbs. 0.13 Bundle/ 3.5 COST INFORMATION (WAC) (\$) 8/13/2021	Dimension Depth 1.9 11.75	/ BILL UNIT Rx billing us IFORMATION Ons (US msm Width 1.9 8	Inner/Carton Case iit to pharma Each Gram Milliliter Its.) Height 3.27	Volume (Cube) 11.80	Pieces 1 24



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification					
Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	X Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard					
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:					
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide a. UN/Identification Number b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which:					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS					
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:					
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: DEA #: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP# ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Phone:					
Is the Product	Comments					
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	product in certain states? No If so, which states? Other requirements? Comments?					
Comments:						
MISCELLAI	NEOUS NOTES and/or Image of Product Barcode:					



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method fo	r Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:
F	Name: Phone:	Ships regular ground for 3-10 days receipt:
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:		Overnight receipt available:
Drop Ship service fee billed with each order:		PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class	of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Infor	rmation Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
Mis	scellaneous Notes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?